Naloxone Opioid Overdose Reversal Collaborative Drug Therapy Agreement

As a licensed health care provider authorized to prescribe medication in the State of Washington, I delegate prescriptive authority to each listed licensed pharmacist at Kelley-Ross Pharmacy Group to initiate drug therapy for the treatment or prophylaxis of opioid overdose according to the following protocol. The protocol provides written guidelines for opioid overdose reversal in accordance with the laws (RCW 18.64.011) and regulations (WAC 246-863-100) of the State of Washington.

Purpose: This agreement will provide access to emergency medication that will reverse opioid-induced overdoses.

Patients: This protocol is designed to provide naloxone to any person or entity at risk of having or witnessing an opiate overdose.

Regulations: The following protocol aligns with the intent of the Washington state “911 Good Samaritan” law (ESB 5516) to prevent harm from opioid overdose. The law authorizes any person to obtain and use naloxone, given the fulfillment of certain requirements, and authorizes any person to administer naloxone to a qualifying third party. The law provides immunity from some drug possession charges in drug overdose situations. This protocol is also in alignment with RCW 69.41.095 to increase access for both bystanders and entities to have and administer naloxone in anyone suspected of experiencing an opioid-related overdose.

Procedure:

1) Prior to Prescribing and Dispensing, the Pharmacist will assess the patient or entity’s need for take-home naloxone and determine whether they meet protocol criteria.

2) Patients must be provided overdose intervention education during the counseling/training session and supportive material, similar to that provided in Appendix 1. This education must be in accordance with Washington State regulations regarding dispensing of naloxone and may include:
   - overdose prevention
   - overdose signs and symptoms
   - calling 911/activating the emergency response
   - airway and breathing assessment
   - the recovery position
   - naloxone storage and administration
   - post-overdose follow-up and care

   Initial education content and continued counselling will be provided according to the professional judgement of the pharmacist to ensure the individual has an understanding of how to respond to an overdose appropriately.

3) Pharmacists will enter and maintain patient/entity demographic and prescription-related information in the pharmacy management system. All patient/entity interactions resulting in a prescribing and dispensing event will be documented within the system.
4) Prescriptions dispensed under this protocol will be readily identifiable by Pharmacist National Provider Identifiers and Naloxone National Drug Codes in the pharmacy management database.

5) Pharmacy staff will be available to answer patient questions during regular business hours and will direct patients to call 911 if they have any questions or concerns outside of business hours.

Products:

Naloxone, Narcan IN, Evizo, and devices required for use of dispensed products such as nasal atomizers and syringes are able to be prescribed under this protocol. If any naloxone opioid overdose reversal products become commercially available while this protocol is in place, they may also be prescribed. A prepared overdose rescue kit must always contain two doses of naloxone. Naloxone drug information is included in Appendix 2 for reference.

Pharmacist Training:

All pharmacists listed on this protocol must read the protocol completely and review and understand the available patient education materials. Specific materials may include, but are not limited to, those found in Appendix 3. Additional information and materials are available at www.stopoverdose.org.

Documentation, Quality Assurance and Reporting:

On an annual basis, the authorizing prescriber and the pharmacist will perform a quality assurance review of the prescribing decisions according to mutually acceptable criteria. Pharmacists will also submit required documentation to the prescriber named below for quality control evaluation after dispensing has concluded.

Terms: This protocol will be in effect for two years unless rescinded earlier in writing to the Washington State Pharmacy Quality Assurance Commission by either party. Any modification of the protocol shall be treated as a new protocol and filed with the Washington State Pharmacy Quality Assurance Commission.

- The pharmacists shall document all drug therapy initiated under this protocol.
- As the authorizing prescriber, I or authorized staff under my supervision will be available to review the drug therapy initiated by the pharmacists.
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References

1. Public Health-Seattle and King County (2009). Drug-caused death data. Data analyzed by Caleb Banta-Green, University of Washington, Alcohol and Drug Abuse Institute, Seattle, WA.


## 1. Naloxone Patient Training

| Overdose Risk factors | - Tolerance and abstinence (jail, detox)  
| - Mixing drugs  
| - Using alone  
| - Variation in strength/quality  
| - Prior overdose  |
|-----------------------|--------------------------------------------------------------------------------|
| Overdose prevention techniques | - Educate those you use with and make a plan!  
| - Purity testing, tie-released gradual injecting, know the source,  
| - keep naloxone next to you, don’t use alone, control own high  
| - Know your tolerance, Risks of Mixing Drugs  |
| Signs of Overdose: | - Unresponsive to yelling, stimulation, or sternal rub  
| - Slow or no breathing  
| - Snoring/gurgling/choking sounds or turning blue  |
| A & B of Life: airway & breathing | - Airway: remove gum, food, anything in mouth  
| - Breath: if stopped or slowed breathing, you must breathe for them (rescue breathing)  
| - If you must leave the person, call 911 and place in recovery position  |
| Call for help | - 911 / Yell!  
| - Good Samaritan law  |
| Rescue Breathing | - On back, tip chin into air to open up airway  
| - Clear mouth and pinch off nose  
| - Seal mouth over theirs  
| - 2 breaths to begin, then one every 5 seconds  |
| Naloxone | - Store away from light and at room temperature  
| - Keep it with your supply & tell people you get high with where it is  
| - Spray about half up each side of the nose  
| - Breathe for them until it starts working  
| - Give 2nd dose in 2-5 minutes  
| - If second dose doesn't work in five minutes, something else is wrong, call 911  |
| Return of Overdose | - Naloxone lasts 30-90 minutes  
| - Heroin overdose may last 2 hours  
| - Methadone overdose may last 24 hours – call 911  
| - Multi-drug overdose (alcohol, benzos, cocaine) could be more dangerous - get to a hospital  |
2. Patient Information

### Naloxone for Overdose Prevention

<table>
<thead>
<tr>
<th>Field</th>
<th>Information</th>
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<tbody>
<tr>
<td>Patient name</td>
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<tr>
<td>Date of birth</td>
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<tr>
<td>Patient address</td>
<td></td>
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<tr>
<td>Patient city, state, ZIP code</td>
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<tr>
<td>Prescriber name</td>
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<tr>
<td>Prescriber address</td>
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<tr>
<td>Prescriber city, state, ZIP code</td>
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<tr>
<td>Prescriber phone number</td>
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**Naloxone HCl 0.4 mg/mL (Narcan)**  
1 x 10 mL as one flip-top vial (NDC 0409-1219-01) OR  
2 x 1 mL single dose vials (NDC 0409-1215-01)  

- **Refills:** ________
- **Intramuscular (IM) syringe, 23 G, 3cc, 1 inch**
- **Qty:** ________  
- **Sig:** For suspected opioid overdose, inject 1 mL IM in shoulder or thigh. Repeat after 3 minutes if no or minimal response.  
- **Prescriber signature**  
- **Date:** ________

### Signs of an overdose
- Slow or shallow breathing
- Gasping for air when sleeping or while standing
- Pale or blue skin
- Slow heartbeat, low blood pressure
- Won’t wake up or respond (sub kneath or sternum)

### Call 911 for help
All you have to say:
- Someone is unresponsive and not breathing.
- Give clear address and location.

### Airway
Make sure nothing is inside the person’s mouth.

### Rescue breathing
Oxygen may be needed. Breathe for them.
- One hand on chin, tilt head back, pinch nose closed.
- Make a seal over mouth & breathe in 1 breath every 5 seconds.
- Chest should rise and stomach.

### Evaluate
- Are they alive? Can you get naloxone and prepare it quickly enough that they won’t go too long without your breathing assistance?

### How to Avoid Overdose
- Only take medicine prescribed to you
- Don’t take more than instructed
- Call a doctor if your pain gets worse
- Never mix pain meds with alcohol
- Avoid sleeping pills when taking pain meds
- Dispose of unused medications
- Store your medicine in a secure place
- Learn how to use naloxone
- Teach your family and friends how to respond to an overdose

### Prepare naloxone
- Remove cap from naloxone and uncover needle.
- Insert needle through rubber plug, with bottle upside down.
- Pull back on plunger and take up 1 cc into the syringe.
- Don’t worry about air bubbles (they aren’t dangerous in muscle injections)

### Muscular injection
Inject 1 cc of naloxone into a big muscle (shoulder or thigh)

<table>
<thead>
<tr>
<th>Step</th>
<th>Instructions</th>
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<tbody>
<tr>
<td>1.</td>
<td>Continue rescue breathing</td>
</tr>
<tr>
<td>2.</td>
<td>Give another shot of naloxone in 3 minutes if no or minimal breathing or respiratory</td>
</tr>
<tr>
<td>3.</td>
<td>Naloxone wears off in 30-90 minutes</td>
</tr>
<tr>
<td>4.</td>
<td>Comfort them; withdrawal can be unpleasant</td>
</tr>
<tr>
<td>5.</td>
<td>Get them medical care and help them not use more opiates right away</td>
</tr>
<tr>
<td>6.</td>
<td>Encourage survivors to seek treatment if they feel they have a problem</td>
</tr>
</tbody>
</table>
**How to Avoid Overdose**

- Only take medicine prescribed to you
- Don't take more than instructed
- Call a doctor if your pain gets worse
- Never mix pain meds with alcohol
- Avoid sleeping pills when taking pain meds
- Dispose of unused medications
- Store your medicine in a secure place
- Learn how to use naloxone
- Teach your family + friends how to respond to an overdose

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<table>
<thead>
<tr>
<th>Are they breathing?</th>
<th>Call 911 for help</th>
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</thead>
<tbody>
<tr>
<td><strong>Signs of an overdose:</strong></td>
<td>All you have to say:</td>
</tr>
</tbody>
</table>
| - Slow or shallow breathing | "Someone is unresponsive and not breathing."
| - Gasping for air when sleeping or weird snoring | Give clear address and location. |
| - Pale or bluish skin | |
| - Slow heartbeat, low blood pressure | |
| - Won't wake up or respond (rub knuckles on sternum) | |

**Airway**

Make sure nothing is inside the person's mouth.

**Rescue breathing**

Oxygen saves lives. Breathe for them.

One hand on chin, tilt head back, pinch nose closed.

Make a seal over mouth & breathe in

1 breath every 5 seconds

Chest should rise, not stomach

---

**Prepare Naloxone**

Are they any better? Can you get naloxone and prepare it quickly enough that they won't go for too long without your breathing assistance?

1. Pull or pry off yellow caps
2. Pry off red cap
3. Grip clear plastic wings.
4. Gently screw capsule of naloxone into barrel of tube.
5. Insert white cone into nostril; give a short, vigorous push on end of capsule to spray naloxone into nose; one half of the capsule into each nostril.
6. If no reaction in 3 minutes, give the second dose.

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**Evaluate + support**

- Continue rescue breathing
- Give another 2 sprays of naloxone in 3 minutes if no or minimal breathing or responsiveness
- Naloxone wears off in 30-90 minutes
- Comfort them; withdrawal can be unpleasant
- Get them medical care and help them not use more opiate right away
- Encourage survivors to seek treatment if they feel they have a problem

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**Poison Center**

1-800-222-1222

(free & anonymous)

**For More Info**

PrescribeToPrevent.com
Appendix 2. Naloxone Drug Information

Complete or Partial Reversal of Opioid Depression

Naloxone prevents or reverses the effects of opioids including respiratory depression, sedation and hypotension. Naloxone is an essentially pure opioid antagonist, i.e., it does not possess the “agonistic” or morphine-like properties characteristic of other opioid antagonists. When administered in usual doses and in the absence of opioids or agonistic effects of other opioid antagonists, it exhibits essentially no pharmacologic activity.

Naloxone has not been shown to produce tolerance or cause physical or psychological dependence. In the presence of physical dependence on opioids, naloxone may produce withdrawal symptoms. Opioid withdrawal symptoms may appear within minutes of naloxone administration and subside in about 2 hours. The severity and duration of the withdrawal syndrome are related to the dose of naloxone and to the degree and type of opioid dependence. Naloxone antagonizes opioid effects by competing for the μ-opioid receptor site in the brain.

Indications and Usage for Naloxone

Naloxone is indicated for the complete or partial reversal of severe opioid depression, including severe respiratory depression, inability to protect their airway, or unresponsiveness. Opioids are natural and synthetic compounds, including propoxyphene, methadone and certain mixed agonist-antagonist analgesics: nalbuphine, pentazocine, butorphanol, and cyclazocine.

Naloxone Dosage and Administration

Intranasal administration via mucosal atomizer device (MAD) has similar bioavailability to IV administration. The nasal mucosal route is optimal for: direct absorption via the vascular plexus of the nose, into the CSF, directly entering the circulation and avoiding the portal circulation; avoidance of destruction by digestive enzymes in the stomach and small intestine. Intramuscular administration has a slightly slower onset of action compared to intravenous administration and a more rapid response than intra-nasal administration. Intramuscular administration produces a more prolonged effect than intravenous administration.

Contraindications

Naloxone is contraindicated in patients known to be hypersensitive to naloxone.

Warnings

1. Repeat Administration

The patient who has satisfactorily responded to naloxone should be kept under continued surveillance for 2 – 3 hrs after the last dose. If an initial dose of naloxone does not successfully reverse an overdose, a second dose may be administered 3-5 minutes after the initial dose. Since the duration of action of some opioids may exceed that of naloxone, repeated doses of naloxone may be necessary.
2. Respiratory Depression due to Other Drugs

Naloxone is not effective against respiratory depression due to non-opioid drugs. Reversal of respiratory depression by super potent opioids such as fentanyl or by partial agonists or mixed agonist/antagonists, such as buprenorphine and pentazocine, may be inadequate or require higher doses of naloxone. If an incomplete response occurs, respirations should be mechanically assisted as clinically indicated.

Precautions

1. General

In addition to naloxone, other resuscitative measures such as maintenance of an open airway, artificial ventilation, cardiac massage, and vasopressor agents may be required to counteract some effects of acute, severe opioid poisoning.

2. Drug Interactions

Large doses of naloxone may be required to antagonize buprenorphine since the latter has a long duration of action due to its slow rate of binding and subsequent slow dissociation from the opioid receptor. Buprenorphine antagonism is characterized by a gradual onset of the reversal effects and a decreased duration of action of the normally prolonged respiratory depression.

Use in Pregnancy

1. Teratogenic Effects: Pregnancy Category C

Teratology studies conducted in mice and rats demonstrated no embryotoxic or teratogenic effects due to naloxone. There are, however, no adequate and well-controlled studies in pregnant women.

2. Non-teratogenic Effects

Risk-benefit must be considered before naloxone is administered to a pregnant woman who is known or suspected to be opioid-dependent since maternal dependence may often be accompanied by fetal dependence. Naloxone crosses the placenta, and may precipitate withdrawal in the fetus as well as in the mother.

Geriatric Use

Reported clinical experience has not identified differences in responses between the elderly and younger patients.

Adverse Reactions

Abrupt reversal of opioid effects in persons who are physically dependent on opioids may precipitate an acute opioid withdrawal syndrome. The acute opioid withdrawal syndrome may include: body aches, fever, sweating, runny nose, sneezing, piloerection, yawning, weakness, shivering or trembling, nervousness, restlessness or irritability, diarrhea, nausea or vomiting, abdominal cramps, increased blood pressure, tachycardia.
A patient who develops a suspected adverse reaction to naloxone should call the pharmacy to report it. Pharmacists can recommend symptom management of the reaction, and/or patient referral. Development of life-threatening symptoms should be immediately referred to the closest emergency room or urgent care clinic. Pharmacists should then report the adverse reaction to the FDA at MedWatch, found online at https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm or 1-800-FDA-1088. Patients can also report suspected adverse drug reactions directly to the FDA at MedWatch.

Appendix 3: Training Outline

1. What is an overdose?
   a. Opioids = stop breathing
   b. Stimulants = heart stops, seizures, stroke
2. Risk factors for opioid OD
   a. Loss of tolerance
      i. Period of sobriety
      ii. Physical health (sick/weight loss)
      iii. Prevention: know your tolerance
   b. Mixing drugs
      i. Benzodiazepines
      ii. Speedballs
      iii. Prevention: one at a time, don’t mix highest risk
   c. Variation in strength/quality
      i. Prevention: Test shots, release tourniquet, know your supply
   d. Using alone
      i. Prevention: use with friends, leave door unlocked, make OD plan
3. Difference between deep nod and OD?
   a. Unresponsive to yelling or stimulation
   b. Slow or no breathing
   c. Snoring/gurgling
   d. Turning blue (especially lips and fingernails)
   e. Slow heartbeat/pulse
4. Steps for responding to an opioid OD
   a. Stimulation/responsiveness (noise, sternum rub)
   b. Check breathing and respond (open airway)
   c. Recovery position
   d. Check for pulse
   e. Call for help
   f. Administer Narcan
      i. Nasal administration option
      ii. How much Narcan?
   g. Rescue breathing
   h. Aftercare
5. Good Samaritan Law
6. Storage
7. Logistics
   a. Prescription and refills